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EXAMINER	
OLSON, ERIC	

ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,047	SAITO ET AL.	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-12 and 15-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-12 and 15-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This office action is a response to applicant's amendment and remarks submitted February 20, 2008 wherein claim 11 is amended, claims 1-6, 13, and 14 are cancelled, and new claims 17 and 18 are introduced.

This application is a national stage application of PCT/JP03/09324, filed July 23, 2003, which claims priority to foreign applications JP2002-213305, filed July 23, 2002, and JP2003-50739, filed February 27, 2003.

Claims 7-12 and 15-18 are pending in this application.

Claims 7-12 and 15-18 as amended are examined on the merits herein.

Applicant's amendment, submitted February 20, 2008, with respect to the rejection of instant claims 11 and 12 under 35 USC 112, first paragraph, for lacking enablement for a method of phosphorylating dextran in formaldehyde solvent, has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to no longer require the use of formaldehyde solvent. Therefore the rejection is withdrawn.

Applicant's amendment, submitted February 20, 2008, with respect to the rejection of instant claims 1-4, 11, and 12 under 35 USC 103(a) for being obvious over JP52028583, has been fully considered and found to be persuasive to remove the rejection as claims 1-4 have been cancelled and the rejection of claims 11 and 12 are

moot in view of the amendment to said claims and the new rejection under 35 USC 102 necessitated thereby. Therefore the rejection is withdrawn.

Applicant's amendment, submitted February 20, 2008, necessitates the following new grounds of rejection:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a disease, does not reasonably provide enablement for a method of preventing a disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed invention is drawn to a therapeutic method for treatment or prevention of a disorder. In the absence of an explicit definition in Applicant's specification, the claims are given their broadest reasonable interpretation. See MPEP 2111. Merriam-Webster's Collegiate Dictionary (reference included with PTO-892) defines "prevent" as meaning, "to deprive of power or hope of acting or succeeding," or "to keep from happening or existing." This definition is taken as representing the ordinary usage of the term "preventative". In order to deprive something of power or hope of acting or succeeding, the preventative agent must be completely effective. "Prevention" as recited in the instant claims, is interpreted to mean the complete and total blocking of all symptoms of a disorder for an indefinite period of time. Merely slowing the onset of disease or making the disease less likely would still leave it with "power or hope of acting or succeeding," and thus not qualify as prevention.

The state of the prior art: Various dietary polysaccharides, including negatively charged and phosphorylated polysaccharides, are known in the art to exert certain biological effects, including being useful for treating disease. They are not, however, known to be useful for preventing any disease in the sense described above under the heading Nature of the Invention.

In general, preventing infectious disease or allergies, according to the definition of prevention given below under the heading "breadth of the claims" is not possible as these conditions are linked to exposure to an external pathogenic agent or allergen which triggers the disease. No chemical or other active agent can control a subject's surrounding to prevent exposure to a sufficiently strong allergen or infectious agent.

Also, both infectious agents and allergens are extremely diverse and no singe compound can be expected to perfectly block the actions of each and every one. More generally, prevention of any disorder in the sense being used herein is not a recognized clinical outcome in the art, as no treatment is perfectly effective.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: Prevention of a disease is not the same as treatment of said disease. In order to prevent a disease, as opposed to merely delaying or reducing its symptoms, a treatment must either render the subject completely resistant to said disease after a single treatment or a limited number of treatments, or else, when continued indefinitely, continue to completely suppress the occurrence of said disease. In order to practice a preventative method, one of skill in the art must know the answer to several questions in addition to the effectiveness of the therapy in short-term relief of symptoms, including:

1) What is the duration of a single course of therapy? How often must the therapy be administered to completely suppress the disease?

2) Does the subject develop tolerance to the therapy over time? Does the disease eventually progress to a point where the therapy is unable to completely suppress all symptoms? For example, will a metastatic cancer eventually adapt to overcome treatments directed to preventing it from metastasizing into the bone? Or will a case of osteoporosis or rheumatoid arthritis ultimately progress to a point where symptoms develop regardless of which therapy is administered.

3) What are the long-term effects of the therapy? Does it cause progressive damage to the kidneys, liver, or other organs? Does the active agent accumulate in the subject's tissues? Is the minimum dose necessary to completely prevent the disease safe for long-term administration? Are there any steps that can be taken to reduce side effects?

For this reason, many therapies which are suitable for short-term relief of symptoms are not suitable for lifelong prevention of disease. For example, antibiotics, chemotherapeutics, and antiviral drugs are not normally administered to healthy subjects in order to prevent the development of infection or cancer.

The Breadth of the claims: In the absence of an explicit definition in Applicant's specification, "Prevention" as recited in the instant claims, is interpreted to mean the complete and total blocking of all symptoms of a disorder for an indefinite period of time. Any therapy which merely reduces the number or severity of symptoms, or which is effective for a period shorter than the subject's remaining lifespan, is considered to be ineffective at preventing a disorder.

The amount of direction or guidance presented: No guidance is given in the specification suggesting any reason to believe that administration of a phosphorylated dextran can achieve complete prevention of infectious disease, allergy, or any other condition.

The presence or absence of working examples: No working examples are given.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as the prevention of disease. See MPEP 2164.

The quantity of experimentation necessary: As mentioned above, the short-term usefulness of a therapy for relief of symptoms is no guarantee of its long-term usefulness for prevention of disease. Because no guidance is given for the use of the claimed therapeutic method for the long-term prevention of disease, one skilled in the art wishing to practice the invention would be unable to do so without first gathering information as to the long-term effectiveness of the therapy. In particular, one skilled in the art, in order to practice the invention for prevention of disease, would need to know whether the preventative effect remains potent over the long term.

In order to answer these questions in the absence of any existing data, one skilled in the art, in order to practice the invention, would undertake long-term animal tests, preferably over a period of years, preferably involving a relatively long-lived experimental animal such as dogs or monkeys, or a human clinical trial. Animal experiments include, along with induction of the disease state, administration of the potential pharmaceutical compound and collection and analysis of data, additional burdens associated with compliance with animal welfare regulations, care, feeding, and other maintenance of the animals, dissection of dead animals to collect data, and disposal of dead animals after the protocol is finished. Administering the claimed compounds for a period of years to a suitable subject population is an undue amount of experimentation needed in order to practice the full range of the claimed invention. As

prevention in the full sense is an extremely high bar for any clinical outcome, there is no reason to believe that the therapy would be successful, and any actual success would be a surprising and unpredictable result.

Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the nature of the invention and the unpredictability of the art, Applicants fail to provide information sufficient to practice the claimed invention for the prevention of any disorder including those recited in instant claims 17 and 18.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 7-9, 17, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by King (US patent publication 2004/0224922, cited in PTO-892).

King discloses a charged dextran, namely dextran phosphate, that decreases mucus viscoelasticity and increases mucociliary clearability. (p. 2 paragraph 0015) This phosphorylated dextran can be administered to an animal having a respiratory disorder such as bronchial asthma, in a form comprising an additional pharmaceutically acceptable carrier. (p. 2 paragraphs 0018-0019) The steps disclosed in the reference are the same as in the instant claims, administering the same compound in the same amounts to the same or similar cells or subjects by the same mode of administration. See *Ex parte Novitski* 26 USPQ 2d 1389, 1391 (Bd. Pat. App. & Int. 1993). Note that the claiming of a new use, new function, or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3c. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it relates to the claimed invention herein. Therefore the specific effect of immunopotentiating the cell or inducing blastogenesis or interferon, is seen to be an inherent effect of the prior art method as the method is seen to be identical to the one recited in the instant claims. Therefore King anticipates the claimed invention.

Because Applicant's amendment necessitated this new ground of rejection, by the additional subject limitations of new claims 17 and 18, the rejection is made **FINAL**.

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki et al. (Reference of record in the previous office action, not the same as the Suzuki et al. reference cited in the previous action against claims 1-11 and 13-16) Suzuki et al.

discloses a phosphorylated dextran and a method of making said dextran phosphate by reacting the dextran with polyphosphoric acid and triethylamine in anhydrous formamide. (p. 228, third paragraph) This process includes **all** of the steps recited in instant claim 11 and thus anticipates said claim. Because Applicant's amendment necessitated this new ground of rejection by removing the requirement in claim 11 for the use of formaldehyde as a solvent, the rejection is made **FINAL**.

Claims 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Japanese Patent application JP52028583. (Reference and translation of abstract of record in previous action, herein referred to as '583).

'583 discloses a phosphorylated dextran palmitate and a method of making said dextran by heating dextran in a reaction mixture containing various reagents including polyphosphate, in formamide solution. (abstract) This process includes **all** of the steps recited in instant claim 11 and thus anticipates said claim. Because Applicant's amendment necessitated this new ground of rejection by removing the requirement in claims 11 and 12 for the use of formaldehyde as a solvent, the rejection is made **FINAL**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7-10 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bijlsma et al. (US patent 6686341, cited in PTO-892, also published as WO00/57727, also included with PTO-892).

Bijlsma et al. discloses compositions containing negatively charged non-digestible polysaccharides. (column 1 lines 47-52) These polysaccharides contain negatively charged groups such as phosphate. (column 2 lines 55-62) Polysaccharides that can be modified in this manner include dextrans. (column 2 line 66 – column 3 line 15) These compositions can be administered to a subject to prevent the entrance of toxic or allergenic substances through the tight junctions of the intestinal wall. (column 4 lines 9-21) The negatively charged polysaccharides are administered as foods or supplements, which are seen to include ingredients considered to be pharmaceutical carriers. (column 4 lines 28-35) These compositions can be used to treat allergies and allergic reactions in the intestines. (column 4 lines 36-42) Several compositions containing these polysaccharides are disclosed in columns 6-7. Bijlsma et al. does not teach the specific active ingredient phosphorylated dextran.

It would have been obvious to one of ordinary skill in the art at the time of the invention to practice the invention of Bijlsma et al. with phosphorylated dextran. One of ordinary skill in the art would have been motivated to do so because Bijlsma et al. already discloses phosphate as one of the negatively charged groups that can be used in this method with dextrans. One of ordinary skill in the art would reasonably have expected success because making the specific embodiments of a generic prior art teaching is well within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious. Because Applicant's amendment necessitated this new ground of rejection, by the additional subject limitations of new claims 17 and 18, the rejection is made **FINAL**.

The following rejections of record in the previous office action are maintained:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-11 and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki et al. W (Reference W of record in previous action, the 892 mailed 9/21/2007).

Suzuki et al. W discloses a study of the antitumor effects of Palmitoyl-dextran-phosphate (PDP), dextran phosphate, (DP) and palmitoyldextran (PD) which are known to enhance the antibody response of mice against implanted tumor cells. (p. 3448, left column, paragraphs 2-3) These dextran derivatives were administered to mice *in vivo* in 0.9% saline solution, which is reasonably considered to be a pharmaceutical composition, or for than matter a food composition because it could be orally ingested. (p. 3448, right column paragraph 3 – p. 3449, left column first paragraph) Administering the compound to a mouse comprises contacting the mouse's cells with the compound, and inherently carries out the method and effects of instant claims 7-10, 15, and 16.

The steps disclosed in the reference are the same as in the instant claims, administering the same compound in the same amounts to the same or similar cells or subjects by the same mode of administration. See *Ex parte Novitski* 26 USPQ 2d 1389, 1391 (Bd. Pat. App. & Int. 1993). Note that the claiming of a new use, new function, or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3c. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it relates to the claimed invention herein.

Response to Argument: Applicant's arguments, submitted February 20, 2008, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that the claimed invention differs from the prior art in that the prior art method produced no anti-tumor activity and the claimed method produces an immunopotentiating effect. However, the claims as written do not require an antitumor effect or require that the subject have a tumor. Applicant further argues that the doctrine of inherency does not apply because the method of Suzuki et al. W does not function within the limitations of the claimed process. However, Applicant has not indicated how the method of Suzuki et al. W actually differs from the prior art in terms of the actual steps performed or the subjects they are performed on. The fact that the prior art does not explicitly disclose all of the effects of a method does not differentiate the claimed method from a prior art method that involves the same actual steps as that which is claimed.

Therefore the rejection is deemed proper and made **FINAL**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. R4 (Reference of record in previous action (Reference R4 in 1449 filed 10/26/2005, not the same as the Suzuki et al. reference cited above against claims 7-11 and 15-16) in view of Sacco et al. (Reference of record in previous action) Suzuki et al. R4 discloses a phosphorylated dextran and a method of making said dextran phosphate by reacting the dextran with polyphosphoric acid and triethylamine in anhydrous formamide. (p. 228, third paragraph) Suzuki et al. R4 does not teach a heating step in the reaction.

Sacco et al. discloses a method of phosphorylating dextran comprising heating dextran in the presence of tributylamine and polyphosphoric acid. (p. 194, third paragraph)

It would have been obvious to one of ordinary skill in the art at the time of the invention to carry out the reaction of Suzuki et al. R4 under heating. One of ordinary skill in the art would have recognized that Sacco et al. suggests adding heat to the phosphorylation reaction to speed up the rate of the reaction, since Sacco et al.

describes a similar reaction, using a similar base and solvent, being carried out under heating.

Thus the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted February 20, 2008, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that there would be no motivation for one of ordinary skill in the art to modify the method of Suzuki et al. R4 because Suzuki et al. R4 discloses that dextran phosphates are practically inactive in the inhibition of Sarcoma 180 ascites tumor. However, claims 11 and 12 are not drawn to the inhibition of tumor growth but to the phosphorylation of dextran. The issue at hand is not whether one of ordinary skill in the art would have been motivated to practice a particular therapeutic method with the final product, but whether one of ordinary skill in the art would have been motivated to use heat to accelerate the reaction disclosed by Suzuki et al. R4. In this case, heating is a very common method that is known to accelerate many chemical reactions. The fact that Sacco et al. discloses heating to work for a similar reaction will provide a reasonable expectation that it will work for the reaction of Suzuki et al. R4.

Therefore the rejection is deemed proper and made **FINAL**.

Conclusion

No claims are allowed in this application. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS**

ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
5/9/2008

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623